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EXAMINER	
DIBRINO,M	
ART UNIT	PAPER NUMBER
1644	21

DATE MAILED: 02/13/01

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☑ THE PERIOD FOR RESPONSE:

a) ☐ is extended to run ______________ or continues to run ______________ from the date of the final rejection

b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☑ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☐ Applicant's response to the final rejection, filed ______________ has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☑ The proposed amendments to the claim and /or specification will not be entered and the final rejection stands because:

   a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.

   b. ☑ They raise new issues that would require further consideration and/or search. (See Note). *

   c. ☐ They raise the issue of new matter. (See Note).

   d. ☑ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

   e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

In proposed claim 4, "a site that is cleaved in vivo" requires further consideration &/or search.
* NOTE: In proposed claim 6, "or immunostimulatory fragments of SEQ ID NOS: 1, 2 or 3" " " "
In proposed claim 33, "DRB1*0901, DRB1*1501, DPA1*0202-DPB1*0501" " " "
In proposed claim 32 "class II DR", "class II DQ", "class II DP" " " " "
" DRB1*0901" & "DRB1*1501" in proposed claim 33 are New Matter.
The "site that is cleaved in vivo" in proposed claim 4 is New Matter because said site does not have to be in between T cell epitopes.

2. ☐ Newly proposed or amended claims ______________ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☑ Upon the filing an appeal, the proposed amendment ☐ will be entered ☑ will not be entered and the status of the claims will be as follows:

** (Continued @ bottom of page).

Claims allowed: NONE
Claims objected to: NONE
Claims rejected: 1, 3-7, 10-13, 17-26

However;

☐ Applicant's response has overcome the following rejection(s): ______________

4. ☑ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because The proposed amendment raises issues that require further consideration &/or search, as well as introducing new matter, and will NOT be entered. The rejections of record stand. (See attached)

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficent reasons why it was not earlier presented.

Also, SEQ ID NO: 7 & 14 of Proposed claims 44 & 46, respectively would require a new search.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☐ Other

** "Analog peptides" in proposed claim 48 requires further consideration &/or search.
Proposed claims 35-47 are drawn to a method, rather than a product, and where limitations are recited in the method claims that are identical to limitations mentioned above for the product would also They would require further consideration and/or search and are new matter and/or new search.

Advisory Action continued...

Applicant's declaration under 37 C.F.R. 1.132 filed 1/19/00 is acknowledged.

With regard to Applicant's comments in the amendment after final submitted 1/19/00 and the aforementioned 132 declaration, Applicant's arguments have been fully considered but are not persuasive. Specifically, although Applicant has demonstrated that six of their multi-epitope peptides do not react significantly with sera from 21 patients allergic to cedar pollen or with sera from 8 non-cedar pollen allergic individuals, this does not address the teachings of Rogers et al. Rogers only examined a panel consisting of only five patients' sera by Western Blot and in ELISA assay (Fig. 4 of Rogers) and examined 6 peptides. With regard to the ELISA assay the reactivity of peptide 11-12-13 appears to be artifactual as the more dilute sample (second data point) reacted at a higher level than the less dilute sample (first data point). In any case, Rogers et al clear teach the desirability of making synthetic peptides which do not bind allergen-specific IgE lies in non-induction of release of histamine from allergic basophils, and the skilled artisan would have been motivated to make the said non-IgE reactive synthetic peptides.

With regard to Applicant's comments on page 8 of the said amendment at the last 4 lines, since the proposed claims have not been entered, Applicant's arguments are moot. With respect to Applicant's further comments on page 9, first paragraph, and in response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See in re Keller, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); In re Merck & Co., 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found wither in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and In re Jones, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In the instant case, Komiyama et al teach CryJ1 and CryJ2 are the major allergens of Japanese Cedar Pollen and the usefulness of these proteins for immunotherapy, WO 94/1560 teaches peptides comprising epitopes from peptides which are immunologically related, including Japanese Cedar Pollen allergen. The rejection stands for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marianne DiBrino whose telephone number is (703) 308-0061. The examiner can normally be reached Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

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Group 1640
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February 12, 2001

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